



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,287	09/24/2003	Gary Karlin Michelson	101.0092-02000	6591

22882 7590 06/16/2006

MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,287

Applicant(s)

MICHELSON, GARY KARLIN

Examiner

Thomas C. Barrett

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-96 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues, "Neither Nolan nor Michelson '710, whether alone or in proper combination teach or suggest an implant with upper and lower members having arcuate portions that in the first position are angled to one another over a majority of the length of the implant as recited in independent claim 1 of Applicant's claimed invention." As noted in prior actions, col. 4 lines 21-23 of Nolan discloses that widths 26 and 28 in figure 3 can be of different sizes, which would therefore make the implant frusto-conical in shape with the upper and lower members angled to one another over a majority, if not the entire length of the implant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose an implant

with upper and lower members having arcuate portions that in the first position are angled to one another over **a majority** of the length of the implant as recited in independent claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-72, 74-76 and 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as cited in Applicant's IDS. Nolan discloses an expansile spinal fusion implant with a portion of a frusto-conical shape and an expanding disc (Fig. 17). The implant can be cylindrical or frusto-conical in its unexpanded position. Col. 4 lines 21-23 discloses that widths 26 and 28 in figure 3 can be of different sizes, therefore the shape may be frusto-conical. The implant comprises radial bone-engaging projections. However Nolan does not disclose the radial projections as "adapted for linear insertion". Michelson teaches a fusion implant with radial projections adapted for linear insertion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of radial projections adapted for linear insertion, as taught by Michelson, to an expansile spinal fusion implant as per Nolan, in order to "urge the spinal fusion implant

forward against the solid unremoved bone further resisting dislodgement and controlling motion resulting in an exceedingly stable implantation" (Michelson-col. 9, lines 23-39).

Claims 73 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as above, in further view of Ray et al. (4,961,740). Nolan modified by Michelson discloses an expandable spinal fusion implant however fails to disclose the use of hydroxyapatite as a material for the implant. Ray et al. teaches the use of hydroxyapatite as a material for a spinal fusion implant, which is useful as a bone-inducing substance (col. 4, lines 46-56). It would have been obvious to one of ordinary skill in the art to combine the teaching of hydroxyapatite as a material for a spinal fusion implant, as taught by Ray et al., to the spinal fusion implant as per Nolan/ Michelson, which is useful as a bone-inducing substance. Also Nolan/ Michelson fails to disclose the use of a snap fit cap for the ends of the implant. Ray et al. teaches the use of snap-fit caps for the ends of the implant (col.6, line 56) to retain bone-inducing substance when it is packed into the implant (col. 4, lines 20-23). It would have been obvious to one of ordinary skill in the art to combine the teaching of snap-fit caps for the ends of the implant, as taught by Ray et al., to the spinal fusion implant as per Nolan/ Michelson, to retain bone-inducing substance when it is packed into the implant.

Claims 77-83 and 89-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (6,117,174) in view of Michelson (5,785,710) as above, in further view of what would be obvious to one of ordinary skill in the art. Nolan modified by Michelson discloses an expandable spinal fusion implant however Nolan fails to

Art Unit: 3738

disclose the use of bone, genes coding or bone morphogenetic protein as a material for the implant. It is well known to one of ordinary skill in the art to use bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, to induce bone ingrowth into the implant. It would have been obvious to one of ordinary skill in the art to combine the teaching of bone, genes coding or bone morphogenetic protein as a material for a spinal fusion implant, as is well known in the art, to the spinal fusion implant as per Nolan/ Michelson, to induce bone ingrowth into the implant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett
Examiner
Art Unit: 3738